

## Exhibit #B 510(k) Summary

JAN 13 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) Number is: K081230

### 1. Subject Device Information

**Trade/Proprietary Name:** Trauson Intramedullary Nail including  
Trauson Femoral Nail  
Trauson Retrograde Femoral Nail  
Trauson Retrograde Humeral Nail

**Common Name:** Intramedullary Fixation Rod

**Classification Name:** Rod, Fixation, Intramedullary and Accessories

**Device Class:** II

**Product Code:** HSB

**Regulation Number:** 888.3020

**Review Panel:** Orthopedic

**Intended Use:**

Trauson Intramedullary Nail is intended to be implanted into the intramedullary canal of femur or humerus for alignment, stabilization, fixation of fractures caused by trauma or disease.

### 2. Sponsor Information

TRAUSON (JIANGSU) MEDICAL INSTRUMENT CO., LTD.

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Changzhou, Jiangsu, 213163, CHINA

**Phone:** +86-757-86280075

**Fax:** +86-757-86397179

**Contact Person of the Submission:**

Ms. Diana Hong

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### **3. Predicate Device**

K072161 Biomet Femoral Locking Nail System  
K050241 AOS Humeral Nail

### **4. Device Description**

The Trauson Intramedullary Nail made of medic 11 grade 3 16L stainless steel that meet ASTM F138 - 08 Standard Specification for Wrought 18Chromium-14 Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants. It is intended to be implanted into the intramedullary canal of femur or humerus for alignment, stabilization, fixation of fractures caused by trauma or disease.

The subject devices are not provided sterile. No new materials are used in the development of this device.

### **5. Test Data**

The subject device material only contains Medic 11 grade 3 16L stainless steel that meets ASTM F138 - 08 Standard Specification for Wrought 18Chromium-14 Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants, and the material is medical grade and widely used in the industry which requires no biocompatibility testing. However, the all conducted Biological Evaluation Tests are in compliance with the standards of ISO 10993, "Biological Evaluation of Medical Devices". The compatibility of all the component material in the finished product was provided.

Bench tests of the applicant device are conducted to determine the Torsional properties.

### **6. Substantially Equivalence**

The Applicant device has the same classification information, intended use, sterilization specifications, performance, biocompatibility, chemical specifications and similar physical and mechanical specifications with the predicate device. The only difference between applicant device and predicate device is some physical specifications variant which is too slight to influence the effectiveness and safety. No new question was raised.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Trauson (Jiangsu) Medical Instruments Co., Ltd.  
% Ms. Diana Hong  
Shanghai Midlink Business Consulting Co., Ltd.  
Lane 999, Zhongshan No. 2 Road, Suite 8D, No. 19  
Shanghai  
CHINA 200030

JAN 18 2009

Re: K081230

Trade/Device Name: Trauson Intramedullary Nail

Regulation Number: 21 CFR 888.3020

Regulation Name: Intramedullary Fixation Rod

Regulatory Class: II

Product Code: HSB

Dated: January 9, 2009

Received: January 12, 2009

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Exhibit #A Indication for Use

**510(k) Number:** K081230

**Device Name:** Trauson Intramedullary Nail

**Indications for Use:**

Trauson Intramedullary Nail is intended to be implanted into the intramedullary canal of femur or humerus for alignment, stabilization, fixation of fractures caused by trauma or disease.

Prescription Use ☒   ✓    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

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